

consideration on appeal, and consider the accompanying remarks. Applicant submits concurrently herewith (1) a Declaration by Dr. Donald Braun (hereinafter referred to as the "Braun Declaration"); (2) a mark-up copy of the amended claims pursuant to 37 C.F.R. §1.121; and (3) a Petition for Extension of Time for a period of three months (from February 29, 2001 up to and including May 29, 2001), and (4) a Notice of Appeal, accompanied by the appropriate fee. It is believed that no additional fees are required for these submissions. However, should it be determined that additional fees are required or that any refund is due in connection with this application, the Commissioner is hereby authorized to charge the required fee(s) and/or credit the refund(s) due to Deposit Account No. 04-0100.

Please amend the application as follows:

**IN THE CLAIMS:**

Please amend the claims pursuant to 37 C.F.R. 1.121 as follows (see the accompanying "marked up" version pursuant to 1.121):

Amend claims 43 and 47, as indicated in the accompanying Mark-Up sheet.

Accordingly, the pending claims are as follows:

---

K1

43. (Amended) A composition comprising human tumor cells that:
- (i) are conjugated to a hapten;

(ii) are of the same tumor type as a malignant tumor of a patient for treatment of whom the composition is intended;

(iii) are autologous to said patient; and

101  
wt (iv) have been rendered incapable of growing in the body of a human upon injection therein;

said composition eliciting, when administered together with an adjuvant, an inflammatory immune response against the tumor of said patient, wherein said tumor is not melanoma.

---

44. (Unchanged) A method for treating a malignant tumor in a human patient comprising co-administering to the patient

(a) a composition comprising a therapeutically effective amount of human tumor cells that:

(i) are conjugated to a hapten;

(ii) are of the same tumor type as a malignant tumor of a patient for treatment of whom the composition is intended;

(iii) are autologous to said patient; and

(iv) have been rendered incapable of growing in the body of a human upon injection therein; and

(b) an adjuvant;

wherein said composition elicits at least one of the following upon administration to said patient with the adjuvant: an inflammatory immune response against the tumor of said patient; a delayed-type hypersensitivity response against the tumor of said patient, and activated T lymphocytes that infiltrate the tumor of said patient, wherein said malignant tumor is not melanoma.

---

47. (Amended) A method of treating a malignant tumor in a human patient comprising co-administering to the patient

(a) a composition comprising a therapeutically effective amount of human tumor cells that:

- (i) are conjugated to a hapten;
- (ii) are of the same tumor type as a malignant tumor of a patient

*for* for treatment of whom the composition is intended;

- (iii) are autologous to said patient; and
- (iv) have been rendered incapable of growing in the body of a

human upon injection therein; and

(b) an adjuvant;

wherein said composition elicits at least one of the following upon administration to said patient with the adjuvant: an inflammatory immune response against the tumor of said patient; a delayed-type hypersensitivity response against the

tumor of said patient and activated T lymphocytes that infiltrate the tumor of said patient; and

10<sup>2</sup>  
at

repeating said administration at least six times at spaced apart intervals.

---

49. (Unchanged) The composition of claim 43 wherein said tumor cells are selected from lung, colon, breast, kidney, and prostate tumor cells.

50. (Unchanged) The composition of claim 43 wherein said hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, and N-iodoacetyl-N'-(5 sulfonic 1-naphtyl) ethylene diamine.

51. (Unchanged) The composition of claim 43 wherein said hapten is dinitrophenyl.

52. (Unchanged) The composition of claim 43 further comprising an adjuvant.

53. (Unchanged) The composition of claim 52 wherein said adjuvant is Bacillus Calmette-Guerin.

54. (Unchanged) The composition of claim 43 further comprising a carrier.

55. (Unchanged) The composition of claim 54 wherein said carrier is selected from the group consisting of saline solution and culture medium.

56. (Unchanged) The method of claim 44 wherein said tumor cells are selected from lung, colon, breast, kidney, and prostate tumor cells.

57. (Unchanged) The method of claim 44, wherein said malignant tumor is from a cancer selected from the group consisting of lung cancer, colon cancer, breast cancer, kidney cancer, and prostate cancer.

58. (Unchanged) The method of claim 44 wherein said hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, and N-iodoacetyl-N'-(5-sulfonic 1-naphtyl) ethylene diamine.

59. (Unchanged) The method of claim 44 wherein said hapten is dinitrophenyl.

60. (Unchanged) The method of claim 44 further comprising administering a therapeutically effective amount of cyclophosphamide prior to administration of said composition.

61. (Unchanged) The method of claim 60 wherein said therapeutically effective amount of cyclophosphamide comprises administering a dose of about 300 mg/M<sup>2</sup> of cyclophosphamide prior to administration of said composition.

62. (Unchanged) The method of claim 60 further comprising sensitizing the patient with a therapeutically effective amount of 1-fluoro-2,4-dinitrobenzene prior to administering cyclophosphamide.

64. (Unchanged) The method of claim 44 wherein said adjuvant is *Bacillus Calmette-Guerin*.

65. (Unchanged) The method of claim 47 wherein said tumor cells are selected from melanoma, lung, colon, breast, kidney, and prostate tumor cells.

66. (Unchanged) The method of claim 47, wherein said malignant tumor is from a cancer selected from the group consisting of melanoma cancer, lung cancer, colon cancer, breast cancer, kidney cancer, and prostate cancer.

67. (Unchanged) The method of claim 47 wherein said hapten is selected from the group consisting of dinitrophenyl, trinitrophenyl, and N-iodoacetyl-N'-(5-sulfonic 1-naphtyl) ethylene diamine.

68. (Unchanged) The method of claim 47 wherein said hapten is dinitrophenyl.

69. (Unchanged) The method of claim 47 further comprising administering a therapeutically effective amount of cyclophosphamide prior to administration of said composition.

70. (Unchanged) The method of claim 47, further comprising administering a therapeutically effective amount of cyclophosphamide prior to the first administration of said composition.

71. (Unchanged) The method of claim 69 wherein said therapeutically effective amount of cyclophosphamide comprises administering a dose of about 300 mg/M<sup>2</sup> of cyclophosphamide prior to administration of said composition.